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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,033	05/14/2001	Lars Branden	2921-0128P	8150

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/787,033	BRANDEN ET AL.	
Examiner	Art Unit	
Dave Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action

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The specification has been amended, claims 4-6, 810, 15, 18-20, 22-27 have been amended by the preliminary amendment filed May 14, 2001.

The specification has been amended by the amendment filed August 5, 2002.

Claims 1-27 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-24, 26, drawn to a method delivering a nucleic acid of interest across a biological membrane, and/or direction thereof to a specific location within or on a cell, comprising the use of a synthetic transport entity comprising any structurally any yet unspecified FE/BE/DNA/carrier complex, the synthetic transport itself, and its specific use in gene therapy, classifiable in class 435, subclasses 320.1, 91.4, 325, 455, class 514, subclass 44.

Group II, claims 25, 26, drawn to a genetically modified cell and its use in gene therapy, classifiable in class 424, subclass 93.21.

Group III, claim 27, drawn to the use of a synthetic transport entity comprising any structurally and yet unspecified FE/BE/DNA/carrier complex a method for DNA-vaccination, classifiable in class 514, subclass 44.

Group IV, claim 27, drawn to a use of a genetically modified cell in DNA-vaccination, classifiable in class 424, subclass 93.21.

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The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 (c) states

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.47 (d) also states:

"if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17 (3) (a) and 1.476(c)".

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), Group I is considered the main invention that is drawn to first method of use first mentioned in the claims of the application and the first recited invention drawn to other categories related thereto, *e.g.*, a method for delivering any nucleic acid interest to a cell *in vitro* and/or *in vivo*, and its subgenus of gene therapy as recited in claim 26.

Groups II-IV are drawn to multiple distinct processes of use and multiple distinct products that do not share the same inventive concept as in Group I. The claimed invention of Groups II-IV recite distinct materials and/or method steps that are neither required nor recited in the claimed invention of Group I, and thus have their own special technical features, *e.g.*, gene therapy method of administering a therapeutic cellular product encoded DNA to a target cell (Group I), a genetically modified cell (Group II), a method of DNA vaccination (group III) by administering a DNA vaccine in combination with the synthetic transport entity, and a method of using any genetically modified cell for DNA vaccination.

Each invention is directed to distinct goal, which comprises the use of genus of DNA sequence(s) or cells in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I to IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

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Should Group I or II be elected, restriction is further required under 35 U.S.C. 121 and 372.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) A specifically named species of FE as recited in claims 10, 13, 22, 23 and 24;

Applicant is required, in reply to this action, to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 1, and claims dependent therefrom correspond to all of the species listed above.

The following claim(s) are generic: claim 1, for example.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As the technical feature (polypeptide sequence) linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since the each of the listed FE do not

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share a substantially common structure feature in common with respect to their site of action. Thus, the requirement of unity of the invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Thus, it would be unduly burdensome for the examiner to search all of the claimed inventions being sought in the pending claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (703) 305-3388.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 305-0196.

Dave Trong Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER